

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Didecylmethylpoly(oxyethyl)ammonium propionate

Product type: 8

ECHA/BPC/074/2015

Adopted

8 December 2015

Opinion of the Biocidal Products Committee

on the application for approval of the active substance didecylmethylpoly(oxyethyl)ammonium propionate for product type 8

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 8 of the following active substance:

Common name:	Didecylmethylpoly(oxyethyl)ammonium propionate
Chemical name(s):	Alpha-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl) propionate
EC No.:	None assigned
CAS No.:	94667-33-1
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Lonza Cologne GmbH on 28th March 2004, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation to the Commission on 20th November 2007. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups and the Commission via the Biocides Technical Meetings (TM III in 2009). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at <http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations>, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 11 April 2014.

Adoption of the BPC opinion

Rapporteur: BPC member for Italy

The BPC opinion on the approval of the active substance didecylmethylpoly(oxyethyl)ammonium propionate in product type 8 was adopted on 8 December 2015.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the didecylmethylpoly(oxyethyl)ammonium propionate in product-type 8 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of didecylmethylpoly(oxyethyl)ammonium propionate, which is also known under the synonym Bardap 26, in product type 8. Didecylmethylpoly(oxyethyl)ammonium propionate is a cationic surfactant-type active substance.

Although the degree of ethoxylation is neither defined by the CAS entry nor by the common name and the chemical name, this opinion covers only this active substance with the following constituents:

n = 0	N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate	C3H5O2.C23H50NO	77.5-86.4% w/w (dry weight)
n = 1	N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate	C3H5O2.C25H54NO2	4.7-9.0% w/w (dry weight)
n = 2	N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate	C3H5O2.C27H58NO3	≤0.20% w/w (dry weight)
n: degree of ethoxylation			

Didecylmethylpoly(oxyethyl)ammonium propionate is manufactured as a technical concentrate, i.e. ca. 60% didecylmethylpoly(oxyethyl)ammonium propionate in ethylene glycol, diethylene glycol and water.

Specifications for the reference sources are established.

The physico-chemical properties of didecylmethylpoly(oxyethyl)ammonium propionate and its representative product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

Validated analytical methods for the active substance as manufactured and for the significant impurities are available. Validated analytical methods are required and are available for the relevant matrices soil and water (both drinking and surface water), but additional confirmatory methods are still required.

A harmonised classification does not exist for didecylmethylpoly(oxyethyl)ammonium propionate under the CLP Regulation. The evaluating Competent Authority (eCA) intends to submit the following harmonised classification proposal to ECHA.

The proposed classification and labelling for didecylmethylpoly(oxyethyl)ammonium propionate according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute toxicity (oral) 4 H302 Skin Corrosion 1B H314 Aquatic Chronic 1 H410
Labelling	
Pictograms	GHS05, GHS09
Signal Word	Danger
Hazard Statement Codes	H302: Harmful if swallowed H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effects
M-Factors	M = 10 (for both)
Justification for the proposal	
Based on the results from studies presented in the dossier, classification of didecylmethylpoly(oxyethyl)ammonium propionate was proposed according to the criteria set out in the CLP Regulation (with amendments).	

b) Intended use, target species and effectiveness

Didecylmethylpoly(oxyethyl)ammonium propionate has fair wetting properties, severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides. The field of application of didecylmethylpoly(oxyethyl)ammonium propionate includes wood preservatives for the preventive treatment against wood-destroying insects and against wood-discolouring moulds and fungi. Didecylmethylpoly(oxyethyl)ammonium propionate is used for preventive protection of wood and constructional timbers in use classes 1 to 4A as reported in the Emission Scenario Document for PT 8. As the data submitted were insufficient to allow an evaluation for use classes 3 and 4A, only conclusions could be drawn for use classes 1 and 2.

The representative product is an aqueous solution, with preventive efficacy against wood-destroying basidiomycetes, against soft rot fungi and insects. It is used in dipping and vacuum pressure process applications in wood protection.

The assessment of the biocidal activity of didecylmethylpoly(oxyethyl)ammonium propionate demonstrates that it has a sufficient level of efficacy against the target organisms. The evaluation of the summary data provided in support of the efficacy of the representative product establishes that it may be expected to be efficacious.

From practical experiences with standalone-biocides in this field of application, it is known that local formation of "resistant" fungus strains at the application site may occur. For this reason didecylmethylpoly(oxyethyl)ammonium propionate is normally not used as a unique biocide in anti sapstain formulations. Wood preservative type formulations normally consist of up of two or three different biocides to avoid adaptations or resistances.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

The main critical effects associated with didecylmethylpoly(oxyethyl)ammonium propionate are due to its corrosive properties. The active substance induces severe erythema, desquamation and corrosive eschar in the rabbit skin, and therefore it is classified as corrosive to skin. No specific studies on didecylmethylpoly(oxyethyl)ammonium propionate toxicokinetics and metabolism are available, however, the read across from data on a structurally related compound, namely didecyltrimethylammonium chloride (DDAC), has been accepted. No systemic effects in the absence of local effects were observed in any of the studies. Therefore, only a local risk assessment was considered necessary for the use of didecylmethylpoly(oxyethyl)ammonium propionate.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	Primary or secondary exposure and description of scenario	Exposed group	Conclusion
Mixing and Loading	Primary exposure: 8.4% of didecylmethylpoly(oxyethyl)ammonium propionate in product concentrate Tier 1: without PPE Tier 2: with PPE	Industrial users / Professionals	Acceptable with PPE
Automated dipping application	Primary exposure: 0.7% of didecylmethylpoly(oxyethyl)ammonium in aqueous diluted concentrate Tier 1: without PPE Tier 2: with PPE	Industrial users / Professionals	Acceptable with PPE
Vacuum pressure application	Primary exposure: 0.7% didecylmethylpoly(oxyethyl)ammonium in aqueous diluted concentrate Tier 1: without PPE Tier 2: with PPE	Industrial users / Professionals	Acceptable with PPE
Child playing on weathered structure and mouthing	Secondary exposure	General public	Acceptable

When appropriate risk mitigation measures are in place, including appropriate exposure control measures like engineering controls and PPE the potential risks associated with local effects were acceptable for all uses. No risks were identified from secondary exposure to treated wood by the general public.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	Description of scenario including environmental compartments	Conclusion
Dipping treatment during application	Dipping process is used only to prevent surface growth of organisms for short term storage of wood used internally for buildings and similar applications. Compartments assessed: sewage treatment plant (STP), surface water.	Unacceptable for surface water. Acceptable for STP. Assessment for sediment not feasible.
Dipping treatment during storage	Treated wood is stored in appropriate locations of the treatment plant following the treatment process. Compartments assessed: surface water and groundwater.	Unacceptable for surface water and groundwater. Assessment for sediment and soil not feasible.
Vacuum pressure treatment during application	Vacuum pressure is a process used to apply wood preservative by overcoming the resistance of the wood to deep penetration using pressure. Compartments assessed: STP, surface water.	Unacceptable for surface water. Acceptable for STP. Assessment for sediment and soil not feasible.
Vacuum pressure treatment during storage	Treated wood is stored in appropriate locations of the treatment plant following the treatment process. Compartments assessed: surface water and groundwater.	Unacceptable for surface water and groundwater. Assessment for sediment and soil not feasible.
Bridge over pond (UC 3)	Treated wood in service. Compartments assessed: surface water.	Acceptable for surface water. Assessment for sediment not feasible.
Noise barrier (UC 3)	Noise barrier is made of poles with planks in between. For the Use Class 3, wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting. Compartments assessed: STP, surface water and groundwater.	Unacceptable for surface water at Time 1 (short term) while acceptable at Time 2 (long term). Acceptable for STP and groundwater. Assessment for soil and sediment not feasible.
Fence (UC 3)	A fence is made of poles with planks in between. For the Use Class 3, wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting. Compartments assessed: groundwater.	Unacceptable for groundwater. Assessment for soil not feasible.

House cladding (UC 3)	The house scenario describes a timber or timber clad house. For the calculations, the default value for the height of the claddings is 2.5 m and the circumference of the house is 50 m. For the Use Class 3, wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting. Compartments assessed: groundwater.	Unacceptable for groundwater. Assessment for soil not feasible.
Fence post (UC 4a)	The fence post scenario describes a rectangular fence post of 10 by 10 cm and a length of 2 m, which is buried to a depth of 0.5 m. For the Use Class 4a, wood in contact with ground. Compartments assessed: groundwater.	Acceptable for groundwater. Assessment for soil not feasible.
Transmission pole (UC 4a)	The scenario describes a transmission pole with a default diameter of 25 cm and a default length of 9 m, which is buried to a depth of 2 m. For the Use Class 4a, wood in contact with ground. Compartments assessed: groundwater.	Acceptable for groundwater. Assessment for soil not feasible.

For industrial application by dipping or vacuum pressure impregnation, including storage, for all scenarios, unacceptable risks are identified for aquatic organisms in surface water. No risk is predicted for the micro-organisms in the sewage treatment plant. For the groundwater compartment, unacceptable risks have been identified only following storage. Therefore, risk mitigation measures are proposed to restrict the storage of pre-treated timber to areas of impermeable hard standing or under shelter, so as to prevent direct exposure of the water compartment and allow the recovery of the losses for recycling or appropriate disposal. Moreover, it is proposed to restrict the dipping and vacuum pressure treatment allowing it only to those plants where significant losses can be contained (e.g. no drain connections to storm drains or STP) and appropriately recycled/disposed.

For treated wood in service, unacceptable risks were identified for several scenarios in use class 3 (noise barrier, fence and house cladding) for groundwater or surface water. However, for sediment-dwelling and soil organisms no data are available for didecylmethylpoly(oxyethyl)ammonium propionate, but only for DDAC. Since didecylmethylpoly(oxyethyl)ammonium propionate is not biodegradable, the read across to sediment and soil data (typically from static tests) available for DDAC was not accepted. Therefore, a Predicted No Effect Concentration (PNEC) for the sediment and soil compartment could not be derived. Subsequently, the available information does not permit to perform a risk assessment for the sediment and soil compartment for use classes other than 1 and 2.

Overall Conclusion

Both automated dipping and vacuum pressure application were acceptable for professional users when appropriate risk mitigation measures are considered. These industrial applications, including storage was only acceptable for the environment when appropriate risk mitigation measures are in place. For the in-service life of treated wood exposed to frequent weathering, an unacceptable risk for groundwater is identified in use class 3

(house and fence scenario), while no reliable risk assessment could be performed for soil and sediment organisms due to the lack of ecotoxicological data. With regards to human health and environment safe use for use classes 1 and 2 were identified when appropriate risk mitigation measures are in place.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	Didecylmethylpoly(oxyethyl)ammonium propionate does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	potential P	Didecylmethylpoly(oxyethyl)ammonium propionate does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B	
	Toxic (T)	not T	
Respiratory sensitisation	No classification required. Didecylmethylpoly(oxyethyl)ammonium propionate does not fulfil criterion (b) of Article 10(1)		
Endocrine disrupting properties	Not considered to have endocrine disrupting properties. Didecylmethylpoly(oxyethyl)ammonium propionate does not fulfil criterion (d) of Article 5(1)		
Concerns linked to critical effects	Didecylmethylpoly(oxyethyl)ammonium propionate does not fulfil criterion (e) of Article 10(1)		
Proportion of non-active isomers or impurities	As the proportion of impurities is below 20% didecylmethylpoly(oxyethyl)ammonium propionate does not fulfil criterion (f) of Article 10(1)		

Consequently, the following is concluded:

Didecylmethylpoly(oxyethyl)ammonium propionate does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Didecylmethylpoly(oxyethyl)ammonium propionate does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the 'Note on the principles for taking decisions on the approval of active substances under the BPR'^[1] and in line with 'Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR'^[2] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

On the basis of the available data in February 2014 a public consultation was launched because didecylmethylpoly(oxyethyl)ammonium propionate was regarded as fulfilling both the P and T criteria. However, during the public consultation several uncertainties affecting the data provided were highlighted. It is concluded that didecylmethylpoly(oxyethyl)ammonium propionate is potential P, not B and not T and therefore does not meet criterion (d) of Article 10(1). In order to clarify the P and T status of the substance, further data are considered necessary and these have been requested in section 2.5 of the opinion. It was agreed that didecylmethylpoly(oxyethyl)ammonium propionate should, after these data have been submitted, further assessed by the PBT Expert Group. Depending on the outcome of the PBT Expert Group there may be a requirement for the substance to be considered as a candidate for substitution as identified in the provisions of Article 10(1)(d).

2.2.2. POP criteria

Didecylmethylpoly(oxyethyl)ammonium propionate does not meet the PBT criteria. No potential for long-range environmental transport is expected, either. Subsequently, it is concluded that didecylmethylpoly(oxyethyl)ammonium propionate is not expected to meet the POP criteria.

2.3. BPC opinion on the application for approval of the active substance didecylmethylpoly(oxyethyl)ammonium propionate in product type 8

In view of the conclusions of the evaluation, it is proposed that didecylmethylpoly(oxyethyl)ammonium propionate shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance is 86.1% w/w (dry-weight).
2. The authorisation of biocidal products is subject to the following conditions:
 - a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
 - b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
 - i. industrial and professional users;
 - ii. groundwater for wood in service that will be exposed to frequent weathering.
 - c. In view of the risks identified for surface and ground water, labels and, where provided, safety data sheets of products authorised shall indicate that

^[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from <https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc>)

^[2] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from [https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10\(1\).doc](https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc))

industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

Didecylmethylpoly(oxyethyl)ammonium propionate meets the criteria for classification according to Regulation (EC) 1272/2008 as skin corrosive of category 1B. Therefore, didecylmethylpoly(oxyethyl)ammonium propionate does not meet the conditions in Article 28(1) to allow inclusion in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. Where use of the product may lead to contamination of food and feeding stuffs, an assessment of the risk in food and feed areas may be required at product authorisation. Analytical methods for residues in/on food and/or feedstuffs may be required, too.
2. Local effects from products containing didecylmethylpoly(oxyethyl)ammonium propionate should be addressed by a risk assessment in accordance with existing guidance at product authorisation since the active substance is classified as corrosive.
3. Further data are required if during product authorisation other uses than use class 1 and 2 would become relevant, since no reliable risk assessment could be performed for use classes 3 and 4a due to the lack of ecotoxicological data for soil and sediment organisms.
4. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
 - a. If an unacceptable risk for industrial and professional users is identified, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment;
 - b. An unacceptable risk for groundwater is identified for treated wood exposed to frequent weathering. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of didecylmethylpoly(oxyethyl)ammonium propionate. However, the following information should be provided to the evaluating Competent Authority (Italy) as soon as possible but not later than 6 months before the date of approval of the active substance:

- Additional highly-specific confirmatory methods for didecylmethylpoly(oxyethyl) ammonium propionate residues in soil and water (both drinking and surface water).
- An *Aerobic and Anaerobic Transformation in Soil test* (OECD 307) as well as in aquatic sediment systems (OECD 308) to clarify the P status of didecylmethylpoly(oxyethyl)ammonium propionate.
- A *Daphnia magna* reproduction test as confirmatory data to clarify the T properties of didecylmethylpoly(oxyethyl)ammonium propionate.